

**FILE UNDER SEAL**

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TEXAS

FILED: **1/29/21**  
U.S. DISTRICT COURT  
EASTERN DISTRICT COURT  
DAVID A. O'TOOLE, CLERK

UNITED STATES OF AMERICA EX REL. LIFE  
LEGAL DEFENSE FOUNDATION,

Relator/Plaintiff

v.

ASD SPECIALTY HEALTHCARE, LLC,  
AMERISOURCEBERGEN CORPORATION and  
DANCO LABORATORIES, LLC

Defendants.

NO.: 4:21CV88

**COMPLAINT FOR  
VIOLATION OF THE FALSE  
CLAIMS ACT [31 U.S.C. §3729  
et seq.]**

**FILE IN CAMERA AND  
UNDER SEAL [31 U.S.C.  
§3730(b)(2)]**

**DO NOT ENTER ON PACER  
DEMAND FOR JURY TRIAL**

Relator/Plaintiff Life Legal Defense Foundation (“Relator/Plaintiff”), on behalf of the United States of America (“Government”) alleges based upon personal knowledge, relevant documents, and information and belief, as follows:

1. This is a “reverse false claims” action to recover damages and civil penalties on behalf of the Government arising from the practice of Defendant Danco Laboratories, LLC, in conspiracy with ASD Specialty Healthcare, LLC, a subsidiary of Amerisource Bergen, of failing to properly mark imported drugs, failing to pay customs duties on such unmarked imports, and knowingly falsifying customs documents in order to conceal its obligation to pay those duties.

**PARTIES**

2. Relator/Plaintiff Life Legal Defense Foundation is a not-for-profit corporation with headquarters in Napa, California.
3. Defendant ASD Specialty Healthcare, LLC (“ASD Healthcare”), a subsidiary of AmerisourceBergen, is a specialty pharmaceutical distributor for health care systems. Until it was acquired by AmerisourceBergen in 2018, ASD Healthcare was known as HD Smith. ASD Healthcare’s main headquarters is in Denton County, Texas.

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4. Defendant AmerisourceBergen Corporation is a drug wholesale company with headquarters in Chesterbrook, Pennsylvania.
5. Defendant Danco Laboratories, LLC, (“Danco”) is a limited liability company, with headquarters in New York City, New York.

## **JURISDICTION AND VENUE**

6. The Court has subject matter over this action pursuant to 28 U.S.C. §1331 and 18 U.S.C. §§ 3730(b), 3732.
7. This court has personal jurisdiction over Defendant Danco and ASD Specialty Healthcare by virtue of both regularly transacting business within this District.
8. Venue is proper in the Eastern District of Texas because the main office of ASD Specialty Healthcare is located at 5025 Plano Parkway, Carrollton, Denton County, Texas.

## **THE TARIFF ACT**

9. All goods, including pharmaceuticals, imported into the United States must be “entered” unless specifically exempted. “Entry” means, among other things, that an importer or its agent must file appropriate document with an officer of the United States Customs and Border Protection (“CBP”) that allows CBP to assess the customs duties on the goods being imported into the United States.
10. Under the Tariff Act, 19 U.S.C. §1304(i), goods that are not properly marked with their country of origin are subject to a special category of customs duties, referred to as “marking duties,” which are assessed at “10 per centum ad valorem” and “shall be deemed to have accrued at the time of importation, shall not be construed to be penal, and shall not be remitted wholly or in part nor shall payment therefor be avoidable for any cause.” An importer is liable for these duties.
11. CBP is charged with monitoring and enforcing U.S. trade laws and customs regulations regarding the importation of foreign goods, CBP collects customs duties, including

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marking duties, and under certain circumstances can require unmarked or mismarked goods, if detected, to be properly marked, destroyed, or re-exported.

12. On or about the time of importation, an importer is required to file certain “entry documents” with CBP, which enable CBP to “properly assess duties on the merchandise” and “determine whether any other applicable requirement of law . . . is met.” 19 U.S.C. §1484(a)(1)(B).
13. Such entry documents typically include an entry summary, such as CBP Form 7501 or its electronic equivalent, which requires an importer to describe, inter alia, the country of origin, the value of the merchandise, the tariff classification, and the importer’s estimate of the correct amount of duties, fees, and other charges and exactions. With respect to marking duties, Form 7501 specifically requires importers to record “any other fee, charge, or exaction that applies,” any “estimated duty . . . and any other fees or charges,” owed to the Government, and the “total estimated AD/CVD or other fees or exactions paid.”
14. In addition to filing entry documents, importers must also deposit estimated duties, fees, charges, and exactions owed with CBP on or about the time of importation. 19 U.S.C. §1505(a), 19 C.F.R. §141.03. The amount of duties deposited represented only the importer’s estimate of how much money it owes, but because entries often automatically “liquidate” by statute at the duty rate estimated by the importer, any false information or omissions in entry documents will directly cause marking duties not to be paid. See 19 U.S.C. §1504(a), 19 C.F.R. §159.11.

## THE VIOLATIONS

15. Since at least 2002, Danco has imported the drug Mifeprex from China. Danco was founded specifically for the purpose of importing Mifeprex from overseas, in order to limit in a country and with one or more manufacturers who would not be susceptible to boycott.

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16. Mifeprex is comprised of a single active ingredient, mifepristone. All Mifeprex has been manufactured with mifepristone obtained from a manufacturer outside the United States, most often in China.
17. One or more manufacturing facilities in China manufacture Mifeprex pills and package them into blister packs, which themselves are packaged into cartons.
18. Each year, Danco imports hundreds of thousands of cartons of Mifeprex from China.
19. ASD Healthcare buys Mifeprex from Danco. ASD Healthcare then sells and ships Mifeprex to health care providers, including clinics and individual doctors across the country.
20. Since at least 2002, Danco has failed to label Mifeprex boxes to indicate the country of origin. Danco has also failed to pay marking duties on Mifeprex, as required by 19 U.S.C. §1304(i).

**COUNT ONE**

(Violation of 31 U.S.C. §3729(a) – Avoiding Obligation to Pay)

21. Relator/Plaintiff incorporates by reference each of the preceding paragraphs.
22. Danco knowingly made, used, or cause to be made or used, false records and statements material to an obligation to pay or transmit money or property to the United States Government.
23. These false records and statements included, but may not be limited to, entry documents and representations included therein filed by Danco or its agents on or about the time of importation of the pharmaceuticals from China, the posting of duties owed, and the unmarked packages of pharmaceuticals themselves.
24. Danco knowingly concealed an obligation to pay or transmit money or property to the United States Government by failing to pay the marking duties it owed, submitting false records or statements in connection with the same, and otherwise obscuring the country of origin of its pharmaceuticals.

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25. Danco knowingly and improperly avoided or decreased an obligation to transmit money or property to the United States Government by failing to pay the marking duties it owed and submitting false records or statements in connection with the same.
26. ASD Healthcare and AmerisourceBergen agreed with Danco to use false records and statements in order to conceal Danco's obligation to pay the marking duties it owed.
27. As a result of Danco's, ASD Healthcare's, and AmerisourceBergen's conduct, including these false records or statements, the United States Government incurred damages, including the amount the amount of marking duties that Danco owes but has not paid.

**PRAYER FOR RELIEF**

WHEREFORE, Relator/Plaintiff prays for the following relief:

A) A permanent injunction requiring Defendants to cease and desist from violating the federal False Claims Act;

B) Judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained as a result of Defendants' unlawful conduct;

C) Civil monetary penalties for each false record or statement made, used, or caused to be made or used by Defendants that was material to any obligation to pay or transmit money or property to the United States Government and/or for each instance of Defendants knowingly concealing or knowingly and improperly avoiding or decreasing any obligation to pay or transmit money or property to the United States Government;

D) An award to Relator/Plaintiff pursuant to 31 U.S.C. 3730(d);

E) And award of reasonable attorney's fees, costs, and expenses,

F) Such other and further relief as this Court should find just and proper.

**JURY DEMAND**

Relator/Plaintiff hereby requests a jury trial in this action on all issues triable by jury.

Dated: January 29, 2021

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Respectfully submitted,

By: /s/ Katherine Seiler  
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ATTORNEY FOR RELATOR/PLAINTIFF

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**Certificate of Service**

The undersigned counsel certifies that a Motion to File under Seal has been filed with the Court (via email to [newcaseshm@txed.uscourts.gov](mailto:newcaseshm@txed.uscourts.gov) as per the clerk's instructions) immediately prior to the filing of this Complaint (to the same aforementioned email address as per the clerk's instructions) and that the following are being sent a copy of this Complaint on this the 29th day of January, 2021 via U.S. Mail:

The United States Attorney's Office  
For the Eastern District of Texas  
Attn: Maureen Smith  
600 East Taylor Street, Suite 2000  
Sherman, Texas 75090

Attorney General of the United States  
U.S. Department of Justice  
950 Pennsylvania Avenue, NW  
Washington, DC 20530-0001

/s/ Katherine Seiler